IFW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: John F. Engelhardt et al.

Title: COMPOUNDS AND METHODS FOR PHARMICO-GENE THERAPY OF EPITHELIAL SODIUM CHANNEL ASSOCIATED DISORDERS

Docket No.: 875.085US1	Serial No.: 10/815,557
Filed: March 31, 2004	Due Date: N/A
Examiner: Unknown	Group Art Unit: 1653

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

We are transmitting herewith the following attached items (as indicated with an "X"):

X Return postcard.
X Information Disclosure Statement (2 pgs.), Form 1449 (16 pgs.), and copies of 214 cited documents, including the International Search Report for corresponding PCT Application No. PCT/US2004/009950 (8 pgs.).

If not provided for in a separate paper filed herewith, Please consider this a PETITION FOR EXTENSION OF TIME for sufficient number of months to enter these papers and please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
Customer Number 21186

By: _____
Atty: Janet E. Embretson
Reg. No. 39,665

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 13th day of January, 2006.

JAMES KANYUSIK
Name

_____
Signature

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	John F. Engelhardt et al.	Examiner:	Unknown
Serial No.:	10/815,557	Group Art Unit:	1653
Filed:	March 31, 2004	Docket:	875.085US1
Title:	COMPOUNDS AND METHODS FOR PHARMICO-GENE THERAPY OF EPITHELIAL SODIUM CHANNEL ASSOCIATED DISORDERS		

INFORMATION DISCLOSURE STATEMENT

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

In compliance with the duty imposed by 37 C.F.R. § 1.56, and in accordance with 37 C.F.R. §§ 1.97 *et. seq.*, the enclosed materials are brought to the attention of the Examiner for consideration in connection with the above-identified patent application. Applicants respectfully request that this Information Disclosure Statement be entered and the documents listed on the attached Form 1449 be considered by the Examiner and made of record. Pursuant to the provisions of MPEP 609, Applicants request that a copy of the 1449 form, initialed as being considered by the Examiner, be returned to the Applicants with the next official communication.

Some of the attached documents were discovered as a result of a Search Report in Applicant's corresponding foreign patent application. Enclosed for the Examiner's information are copies of the cited documents and the Search Report.

Pursuant to 37 C.F.R. §1.97(b), it is believed that no fee or statement is required with the Information Disclosure Statement. However, if an Office Action on the merits has been mailed, the Commissioner is hereby authorized to charge the required fees to Deposit Account No. 19-0743 in order to have this Information Disclosure Statement considered.

Pursuant to 37 C.F.R. 1.98(a)(2), Applicant believes that copies of cited U.S. Patents and Published Applications are no longer required to be provided to the Office. Notification of this change was provided in the United States Patent and Trademark Office OG Notices dated October 12, 2004. Thus, Applicant has not included copies of any U.S. Patents or Published Applications cited with this submission. Should the Office require copies to be provided, Applicant respectfully requests that notice of such requirement be directed to Applicant's below-signed representative. Applicant acknowledges the requirement to submit copies of foreign patent documents and non-patent literature in accordance with 37 C.F.R. 1.98(a)(2).

The Examiner is invited to contact the Applicant's Representative at the below-listed telephone number if there are any questions regarding this communication.

Respectfully submitted,

JOHN F. ENGELHARDT ET AL.

By their Representatives,

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. Box 2938
Minneapolis, MN 55402
(612) 373-6959

Date January 12, 2006 By _____
Janet E. Embretson
Reg. No. 39,665

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 13TH day of January, 2006.

Name JAMES KAUKOIK

Signature _____

PTO/SB/08A(10-01)
Approved for use through 10/31/2002. OMB 651-0031
US Patent & Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 16

Complete if Known	
Application Number	10/815,557
Filing Date	March 31, 2004
First Named Inventor	Engelhardt, John
Group Art Unit	1653
Examiner Name	Unknown
Attorney Docket No: 875.085US1	

US PATENT DOCUMENTS

Examiner Initial *	USP Document Number	Publication Date	Name of Patentee or Applicant of cited Document	Filing Date If Appropriate
	US-2002/0197237A1	12/26/2002	Engelhardt, J., et al.	01/22/2002
	US-2002/0076754A1	06/20/2002	Sun, Liangwu, et al.	04/20/2001
	US-2002/0131956A1	09/19/2002	Walsh, C. E., et al.	03/12/2002
	US-2003/0103939A1	06/05/2003	Engelhardt, J. E., et al.	07/12/2002
	US-5,604,090	02/18/1997	Alexander, Ian E., et al.	06/06/1994
	US-5,691,176	11/25/1997	Lebkowski, J. S., et al.	06/02/1995
	US-5,831,068	11/03/1998	Nair, S. K., et al.	08/20/1996
	US-5,834,182	11/10/1998	Alexander, Ian E., et al.	02/25/1997
	US-5,843,742	12/01/1998	Natsoulis, G. , et al.	09/08/1995
	US-6,083,702	07/04/2000	Mitchell, L. G., et al.	08/13/1998
	US-6,156,303	12/05/2000	Russell, D. W., et al.	06/11/1997
	US-6,200,560	03/13/2001	Couto, L. B., et al.	12/22/1999
	US-6,221,349	04/24/2001	Couto, Linda B., et al.	07/30/1999
	US-6,287,569	09/11/2001	Kipps, T. J., et al.	04/06/1998
	US-6,436,392	08/20/2002	Engelhardt, John F., et al.	03/25/1999
	US-6,544,786	04/08/2003	Xiao, Xiao, et al.	10/13/2000

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Foreign Document No	Publication Date	Name of Patentee or Applicant of cited Document	T[2]
	CA-2302627	09/23/2001	Yves, B. , et al.	
	EP-1153612A1	11/14/2001	Tsurou, T. , et al.	
	WO-94/13788A1	06/23/1994	Coruzzi, Laura A., et al.	
	WO-95/07351A1	03/16/1995	Jarrell, Kevin A.	
	WO-95/15384A1	06/08/1995	Johnson, David C., et al.	
	WO-97/22250A1	06/26/1997	Mitchell, Lloyd G.	
	WO-98/09657A2	03/12/1998	Wilson, James M., et al.	
	WO-98/24479A1	06/11/1998	Snyder, R., et al.	
	WO-98/53839A2	12/03/1998	Stoven, V., et al.	
	WO-99/60146A1	11/25/1999	Engelhardt, John F., et al.	
	WO-00/47220A1	08/17/2000	Kenten, J. H., et al.	
	WO-00/75365A2	12/14/2000	Engelhardt, J. F., et al.	
	WO-01/25465A1	04/12/0001	Engelhardt, J. F.	
	WO-01/83692A2	11/08/2001	Hildinger, M., et al.	
	WO-02/087306A2	11/07/2002	Callamaras, N., et al.	
	WO-2004/090145A2	10/21/2004	Engelhardt, J. F., et al.	

EXAMINER **DATE CONSIDERED**

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional) 2 Applicant is to place a check mark here if English language Translation is attached

PTO/SB/08A(10-01)
Approved for use through 10/31/2002. OMB 651-0031
US Patent & Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known	
Application Number	10/815,557
Filing Date	March 31, 2004
First Named Inventor	Engelhardt, John
Group Art Unit	1653
Examiner Name	Unknown

Sheet 2 of 16

Attorney Docket No: 875.085US1

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No [1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
		"(S)-(+)-Camptothecin; 4-Ethyl-4-hydroxy-1H-pyrano[3', 4': 6,7] indolizino [1,2-b] quinoline-3, 14 (4H, 12H) dione", Calbiochem, Camptothecin, Camptotheca acuminata,(October 2, 2000),1-2	
		"Adriamycin; 14-Hydroxydaunomycin, HCl", Calbiochem, Doxorubicin, Hydrochloride, Catalog Number 324380,(October 21, 1998),1-2	
		"Aminoglycoside antibiotic. Inhibits myeloperoxidase-dependent oxidant cell injury", Calbiochem, Tobramycin, Free Base, Catalog Number 614005,(August 26, 1999),1	
		"Cancer Research", Contribution to Society, http://www.bikaken.or.jp/mcrf_e/contributiion,(December 4, 2000),2 pages	
		"Carbobenzoxy-L-leucyl-L-leucinal", Calbiochem, MG-132, Catalog Number 474790,(October 15, 1999),1-2	
		"Drugs for Selection of Genetic Markers Reagents for positive and negative selection of Genes involved in Nucleotide Metabolism", Calbiochem, (March 2002), 6 pgs.	
		"EPA; 20:5 ω-3; 5,8, 11, 14, 17-Eicosapentaenoic Acid", Calbiochem, Eicosapentaenoic Acid, Catalog Number 324875,(December 7, 1998),1-2	
		"Epoxomicin- a potent and selective proteasome inhibitor", Affiniti Research Products Limited, 2 pages	
		"International Search Report for corresponding PCT Application No. PCT/US2004/009950", (Attorney Docket No. 875.085WO1),8 pgs.	
		"LDP-341", Millennium Pharmaceuticals, http://www.biospace.com/ct/detail.cfm?ClinicalID=266404,1 page	
		"Mevinolin; MK-803", Calbiochem, Lovastatin, Catalolg Number 438185,(June 29, 2001),1-2	
		"MK-733", Calbiochem, Simvastatin, Catalog Number 567020,(October 25, 2001),2	
		"Polymer Vectors Endosomal release and cytoplasmic delivery", Endosomal Release, http://web.bham.ac.uk/can4psd4/nonviral/endosome.html,(June 3, 2001),1	
		"Product Data Sheet", Moravek Biochemicals, Inc., M-1535, Ritonavir,(July 12, 2001),1 page	
		"Product Information", Sigma, Cyclosporin A, Sigma Product No. C3662,(October 28, 1996),3 pages	
		"Product Information", Sigma, Bleomycin Sulfate, Sigma Prod. No. B5507,(November 25, 1996),2 pages	
		"Proteasome Inhibitors", Peptides International, Inc., (April 16, 2001),1-2	
		"Tannic Acid, A.C.S. reagent", Sigma, www.sigma-aldrich.com/sacatolog.nsf/productlookup/Aldrich403040?OpenDocument,1 pg.	

EXAMINER **DATE CONSIDERED**

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional) [2] Applicant is to place a check mark here if English language Translation is attached

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known

Application Number	10/815,557
Filing Date	March 31, 2004
First Named Inventor	Engelhardt, John
Group Art Unit	1653
Examiner Name	Unknown

Sheet 3 of 16

Attorney Docket No: 875.085US1

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No [1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
		ADAMS, JULIAN, et al., "Chapter 28. Novel Inhibitors of the Proteasome and Their Theraputic Use in Inflammation", Annual Reports in Medicinal Chemistry, Academic Press, Inc.,(1996),279-288	
		ADAMS, JULIAN, "Proteasome inhibition: a novel approach to cancer therapy", Trends in Molecular Medicine, 8(4), (2002),S49-S54	
		ALBERTS, BRUCE, et al., "Molecular Biology of the Cell", 3rd edition, (1994),618-626	
		ALEXANDER, IAN E., et al., "DNA-Damaging Agents Greatly Increase the Transduction of Nondividing Cells by Adeno-Associated Virus Vectors", Journal of Virology, 68(12), (December 1994),8282-8287	
		ALEXANDER, I E., et al., "Effects of Gamma Irradiation on the Transduction of Dividing and Nondviding Cells in Brain and Muscle of Rats by Adeno-Associated Virus Vectors", Human Gene Therapy, 7(7), (May 1, 1996),841-850	
		ANDRE, PATRICE, et al., "An inhibitor of HIV-1 protease modulates proteasome activity, antigen presentation, and T cell responses", Proc. National Academy of Science USA, vol. 95, (October 1998),13120-13124	
		ARCAMONE, F M., "From the PIgments of the Actinomycetes to Third Generation Antitumor Anthracyclines", Biochimie (Paris), 80(3), (March 1998),201-206	
		BANERJEE, D. , et al., "The Treatment of Respiratory Pseudomonas Infection in Cystic Fibrosis: What Drug and Which Way?", Drugs, 60(5), (Abstract Only),(November 2000),1 pg.	
		BANK, U. , "Review: Peptidases and Peptidase Inhibitors in the Pathogenesis of Diseases", Cellular Peptidases in Immune Functions and Diseases 2, (Edited by Jurgen Langner, et al., Kluwer Academic / Plenum Publishers),(2000),349-378	
		BARTLETT, JEFFREY S., et al., "Infectious entry pathway of adeno-associated virus and adeno-associated virus vectors", Journal of Virology, 74(6), (March 2000),2777-2785	
		BARTLETT, J S., et al., "Targeted adeno-associated virus vector transduction of nonpermissive cells mediated by a bispecific F(ab'γ)$_2$ antibody", Nature Biotechnology, 17, (1999),pp. 181-186	
		BASAK, S , et al., "Infectious Entry Pathways for Canine Parvovirus", Virology, 186(2), (February 1992),368-376	
		BERNS, K. I., et al., "Biology of Adeno-associated Virus", In: Current Topics in Microbiology and Immunology, 218, Springer-Verlag, Berlin: R.W. Compans, et al., (Eds.),(1996),pp. 1-23	
		BERNS, K. I., "Parvovirus Replication", Microbiological Reviews, 54 (3), (Sept. 1990),pp. 316-329	

EXAMINER **DATE CONSIDERED**

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional) [2] Applicant is to place a check mark here if English language Translation is attached

PTO/SB/08A(10-01)
Approved for use through 10/31/2002. OMB 651-0031
US Patent & Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known	
Application Number	10/815,557
Filing Date	March 31, 2004
First Named Inventor	Engelhardt, John
Group Art Unit	1653
Examiner Name	Unknown

Sheet 4 of 16

Attorney Docket No: 875.085US1

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No [1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
		BIES, J. , et al., "Oncogenic activation of c-Myb by Carboxyl-Terminal truncation leads to Decreased Proteolysis by the Ubiquitin-26S proteasome pathway", Oncogene, 14(2), (Abstract Only),(January 16, 1997),1 pg.	
		BOKKALA, SHAILA, et al., "Angiotensin II-induced Down-regulation of Inositol Trisphosphate Receptors in WB Rat Liver Epithelial Cells", Journal of Biological Chemistry, 272(19), (May 9, 1997),12454-12461	
		BONACORSI, STEPHANE, et al., "Comparative In Vitro Activities of Meropenem, Impenem, Temocillin, Piperacillin, and Ceftazidime in Combination with Tobramycin, Rifampin, or Ciprofloxacin against *Burkholderia cepacia* Isolates from Patients with Cystic Fibrosis", Antimicrobial Agents and Chemotherapy, 43(2), (February 1999),213-217	
		BRAND, STEPHEN , et al., "Role of the Proteasome in Rat Indomethacin-Induced Gastropathy", Gastroenterology, 116(4) (1999),865-873	
		BRAVO, LAURA , "Polyphenols: Chemistry, Dietary Sources, Metabolism and Nutritional Significance", Nutrition Reviews, 56(11), (November 1998),317-333	
		BRÖTZ, H. , "The Lantibiotic Mersacidin Inhibits Peptidoglycan Biosynthesis and the Level of Transglycosylation", Eur. J. Biochem., 246(1), (1997),193-199	
		BUGG, C., et al., "SRI6975 Increases Adenovirus Mediated Gene Transfer Through the Apical Surface of Polarized MDCK Cell Monolayers", Cystic Fibrosis Foundation: 2000 North American CF Conference, (November 2000),1	
		CANTIN, ANDRE M., et al., "Aerosolized Prolastin Suppresses Bacterial Proliferation in a Model of Chronic *Pseudomonas aeruginosa* Lung Infection", American Journal of Respiratory and Critical Care Medicine, vol. 160, (1999),1130-1135	
		CHU, Q , et al., "Binding and uptake of Cationic Lipid: pDNA Complexes by Polarized Airway Epithelial Cells", Human Gene Therapy, 10, (1999),pp. 25-36	
		CHUNG, KING-THOM , et al., "Tannis and Human Health: A Review", Critical Reviews in Food Science and Nutrition, 38(6), (1998),421-464	
		CONRAD, C. K., et al., "Safety of single-dose administration of an adeno-associated virus (AAV)-CFTR vector in the primate lung", Gene Therapy, 3(8), (August 1996),658-668	
		COONROD, A , et al., "On the mechanism of DNA transfection: efficient gene transfer without viruses", Gene Therapy, 4, (1997),pp. 1313-1321	
		CROYLE, MARIA, et al., "Development of Novel Formulations that Enhance Adenoviral-Mediated Gene Expression in the Lung in Vitro and in Vivo", Molecular Therapy, vol. 4, no. 1, (July 2001),22-28	
		DESAI, SHYAMAL , et al., "Ubiquitin-dependent Destruction of Topoisomerase I Is Stimulated by the Antitumor Drug Camptothecin", Journal of Biological Chemistry, 272(39), (September 26, 1997),24159-24164	

EXAMINER **DATE CONSIDERED**

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional) 2 Applicant is to place a check mark here if English language Translation is attached

PTO/SB/08A(10-01)
Approved for use through 10/31/2002. OMB 651-0031
US Patent & Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known	
Application Number	10/815,557
Filing Date	March 31, 2004
First Named Inventor	Engelhardt, John
Group Art Unit	1653
Examiner Name	Unknown

Sheet 5 of 16

Attorney Docket No: 875.085US1

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No [1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
		DIETRICH, CORNELIA, et al., "p53-Dependent cell cycle arrest induced by *N*-acetyl-L-leucinyl-*L* -leucinyl-L-norleucinal in platelet-derived growth factor-stimulated human fibroblasts", Proc. of the Nat'l Academy of Sciences of the US, 93(20) (1996),10815-10819	
		DING, WEI, et al., "Proteasome Inhibitor LLnL (MG101) Augments AAV5 Transduction in Polarized Human Airway Epithelia", American Society of Gene Therapy, Abstracts of Scientific Presentations –(Abstract No. 571),(June 5, 2002),1 pg.	
		DING, W., et al., "Second-Strand Genome Conversion of Adeno-Associated Virus Type 2 (AAV-2) and AAV-5 is Not Rate Limiting Following Apical Infection of Polarized Human Airway Epithelia", Journal of Virology, 77(13), (2003),7361-7366	
		DISHART, KATE , et al., "Recombinant Adeno-Associated Virus-2 as a Candidate Gene Delivery Vector for Vein Grafts", American Society of Gene Therapy, Abstracts of Scientific Presentations, (Abstract No. 1107),(June 5, 2002),1 page	
		DONALDSON, S. H., et al., "Regulation of the Epithelial Sodium Channel by Serine Proteases in Human Airways", The Journal of Biological Chemistry, 277(10), (2002),8338-8345	
		DOUAR, A.-M., et al., "Intracellular Trafficking of Adeno-Associated Virus Vectors: Routing to the Late Endosomal Compartment and Proteasome Degration", Journal of Virology, 75(4), (2001),1824-1833	
		DUAN, D. , et al., "A New Dual-Vector Approach to Enhance Recombinant Adeno-Associated Virus-Mediated Gene Expression Through Intermolecular cis Activation", Nature Medicine, 6(5), (2000),595-598	
		DUAN, D. , et al., "Chapter 15: *Trans*-Splicing Vectors Expand the Packaging Limits of Adeno-Associated Virus for Gene Therapy Applications", Methods in Molecular Medicine, Vol. 76: Viral Vectors for Gene Therapy: Methods and Protocols, (2003),287-307	
		DUAN, D. , et al., "Chapter 3 - Adeno-Associated Virus", In: Lung Biology in Health and Disease, Vol. 169 - Gene Therapy in Lung Disease, Albelda, S. M., Editor, Marcel Dekker, Inc.,(2002),51-92	
		DUAN, D. , et al., "Chapter 3 - Dual Vector Expansion of the Recombinant AAV Packaging Capacity", In: Methods in Molecular Biology, Vol. 219: Cardiac Cell and Gene Transfer, Metzger, J. M., Editor, Human Press, Inc., Totowa, NJ,(2003),29-51	
		DUAN, D , et al., "Circular Intermediates of Recombinant Adeno-Associated Virus Have Defined Structural Characteristics Responsible for Long-Term Episomal Persistence in Muscle Tissue", Journal of Virology, 72(11), (1998),8568-8577	

EXAMINER **DATE CONSIDERED**

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional) 2 Applicant is to place a check mark here if English language Translation is attached

PTO/SB/08A(10-01)
Approved for use through 10/31/2002. OMB 651-0031
US Patent & Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known	
Application Number	10/815,557
Filing Date	March 31, 2004
First Named Inventor	Engelhardt, John
Group Art Unit	1653
Examiner Name	Unknown

Sheet 6 of 16

Attorney Docket No: 875.085US1

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No [1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
		DUAN, D. , et al., "Consequences of DNA-Dependent Protein Kinase Catalytic Subunit Deficiency on Recombinant Adeno-Associated Virus Genome Circularization and Heterodimerization in Muscle Tissue", Journal of Virology, 77(8), (2003),4751-4759	
		DUAN, DONGSHENG , et al., "Dynamin is required for recombinant adeno-associated virus type 2 infection", Journal of Virology, 73(12), (December 1999),10371-10376	
		DUAN, D. , et al., "Endosomal processing limits gene transfer to polarized airway epithelia by adeno-associated virus", Journal of Clinical Investigation, 105, (June, 2000),1573-1587	
		DUAN, D. , et al., "Enhancement of Muscle Gene Delivery With Pseudotyped Adeno-Associated Virus Type 5 Correlates With Myoblast Differentiation", Journal of Virology, 75(16), (2001),7662-7671	
		DUAN, D. , et al., "Expanding AAV Packaging Capacity With *Trans*-splicing or Overlapping Vectors: A Quantitative Comparison", Molecular Therapy, 4(4), (2001),383-391	
		DUAN, D. , "Formation of Adeno-Associated Virus Circular Genomes is Differentially Regulated by Adenovirus E4 ORF6 and E2a Gene Expression", Journal of Virology, 73(1), (Jan. 1999),161-169	
		DUAN, D. , "Polarity Influences the Efficiency of Recombinant Adenoassociated Virus Infection in Differentiated Airway Epithelia", Human Gene Therapy, 9, (Dec. 10, 1998),2761-2776	
		DUAN, D , et al., "Response to "Polarity Influences the Efficiency of Recombinant Adenoassociated Virus Infection in Differentiated Airway Epithelia"", Human Gene Therapy, 10, (1999),pp. 1553-1557	
		DUAN, DONGSHENG , et al., "Structural Analysis of adeno-associated virus transduction circular intermediates", Virology, 261(1), (Aug. 1999),8-14	
		DUAN, DONGSHENG , et al., "Structural and functional heterogeneity of intregrated recombinant AAV genomes", Virus Research, 48 (1), (Jan. 1997),pp. 41-56	
		ELLIOTT, P J., et al., "Recent Advances in Understanding Proteasome Function", Current Opinion in Drug Discovery and Development, 5 (2), ISSN: 1367-6733,(1999),484-490	
		ENGELHARDT, J. F., et al., "Direct Gene Transfer of Human CFTR Into Human Bronchial Epithelia of Xenografts With E1-Deleted Adenoviruses", Nature Genetics, 4, (1993),27-34	
		ENGELHARDT, J. F., "The Lung as a Metabolic Factory for Gene Therapy", The Journal of Clinical Investigation, 110(4), (2002),429-432	
		EVERETT, R D., et al., "A viral activator of gene expression functions via the ubiquitin-proteasome pathway", The EMBO Journal, 17 (24), (1998),pp. 7161-7169	

EXAMINER **DATE CONSIDERED**

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional) 2 Applicant is to place a check mark here if English language Translation is attached

PTO/SB/08A(10-01)
Approved for use through 10/31/2002. OMB 651-0031
US Patent & Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known	
Application Number	10/815,557
Filing Date	March 31, 2004
First Named Inventor	Engelhardt, John
Group Art Unit	1653
Examiner Name	Unknown

Sheet 7 of 16

Attorney Docket No: 875.085US1

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	**Cite No [1]**	**Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.**	**T[2]**
		FASBENDER, AL , et al., "Complexes of adenovirus with polycationic polymers and cationic lipids increase the efficiency of gene transfer *in viro* and *in vivo*", The Journal of Biological Chemistry, 272 (10), (March 7, 1997),6479-6489	
		FAYADAT, LAURENCE, et al., "Degradation of Human Thyroperoxidase in the Endoplasmic Reticulum Involves Two Different Pathways Depending on the Folding State of the Protein", Journal of Biological Chemistry, 275(21), (May 26, 2000),15948-15954	
		FENTEANY, G., et al., "Inhibition of Proteasome Activities and Subunit-Specific Amino-Terminal Threonine Modification by Lactacystin", Science, 268, (1995), 726-731	
		FENTEANY, GABRIEL , et al., "Lactacystin, Proteasome Function, and Cell Fate", Journal of Biological Chemistry, 273(15), (April 10, 1998),8545-8548	
		FERRARI, F K., et al., "Second-Strand Synthesis Is a Rate-Limiting Step for Efficient Transduction by Recombinant Adeno-Associated Virus Vectors", Journal of Virology, 70(5), (1996),3227-3234	
		FIGUEIREDO-PEREIRA, MARIA E., et al., "The antitumor drug aclacinomycin A, which inhibits the degradation of ubiquitinated proteins, shows selectivity for the chymotrypsin-like activity of the bovine pituitary 20 S proteasome", Journal of Biological Chemistry, 271(28), (July 12, 1996),16455-16459	
		FISHER, KRISHNA , et al., "Recombinant adeno-associated virus for muscle directed gene therapy", Nature Medicine, 3 (3), (March 1997),pp. 306-312	
		FISHER, K J., et al., "Transduction with recombinant adeno-associated virus for gene therapy is limited by leading-strand synthesis", Journal of Virology, 70(1), (Jan., 1996),520-532	
		FLOTTE, T. R., et al., "Adeno-Associated Virus Vector Gene Expression Occurs in Nondividing Cells in the Absence of Vector DNA Integration", American Journal of Respiratory Cell and Molecular Biology, 11, (1994),pp. 517-521	
		FLOTTE, T. R., et al., "Chapter 40 - Adeno-Associated Viral Vectors for CF Gene Therapy", In: Methods in Molecular Medicine, 70, (2002),599-608	
		GABIZON, ALBERTO, "Long-circulating liposomes for drug delivery in cancer therapy: a review of biodistribution studies in tumor-bearing animals", Advanced Drug Delivery Reviews, (1997),337-344	
		GABIZON, ALBERTO, et al., "Preclinical Studies with Doxorubicin Encapsulated in Polyethyleneglycol-Coated Liposomes", Journal of Liposome Research, 3(3), (1993),517-528	
		GARBER, KEN , "Taking Garbage In, Taking Cancer Out?", Science, 295, (January 25, 2002),612-613	
		GOLDBERG, A L., et al., "New insights into proteasome function: from archaebacteria to drug development", Chemistry & Biology, 2(8), (1995), 503-508	

EXAMINER **DATE CONSIDERED**

Substitute Disclosure Statement Form (PTO-1449)

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional) 2 Applicant is to place a check mark here if English language Translation is attached

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known	
Application Number	10/815,557
Filing Date	March 31, 2004
First Named Inventor	Engelhardt, John
Group Art Unit	1653
Examiner Name	Unknown

Sheet 8 of 16

Attorney Docket No: 875.085US1

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No [1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
		GOTTLIEB, T A., et al., "Actin Microfilaments Play a Critical Role in Endocytosis at the Apical but not the Basolateral Surface of Polarized Epithelial Cells", The Journal of Cell Biology, 120 (3), (1993), 695-710	
		GRUCHALA, MARCIN, et al., "Adeno-Associated Virus-Mediated Gene Transfer into Normal Rabbit Arteries. Assessment of the Tie and CMV Promoters and the Antiproteasome Treatment with MG-132", American Society of Gene Therapy, Abstracts of Scientific Presentations, (Abstract No. 1110), (June 5, 2002),1 page	
		HALBERT, C. L., "Transduction by Adeno-Associated Virus Vectors in the Rabbit Airway: Efficiency, Persistence, and Readministration", Journal of Virology, 71(8), (Aug. 1997),pp. 5932-5941	
		HANSEN, J., et al., "Adeno-Associated Virus Type 2-Mediated Gene Transfer: Altered Endocytic Processing Enhances Transduction Efficiency in Murine Fibroblasts", Journal of Virology, 75(9), (2001),4080-4090	
		HANSEN, J. , et al., "Impaired Intracellular Trafficking of Adeno-Associated Virus Type 2 Vectors Limits Efficient Transduction of Murine Fibroblasts", Journal of Virology, 74(2), (2000),992-996	
		HASEGAWA, S., et al., "Microtubule involvement in the intracellular dynamics for gene transfection mediated by cationic liposomes", Gene Therapy, 8, (2001),1669-1673	
		HONG, J. , et al., "Identification of SRI6975, A Compound that Enhances Adenovirus-Mediated Gene Expression in Polarized Epithelial Cells", Cystic Fibrosis Foundation: 2000 North American CF Conference, (November 2000), 1-2	
		HOSSEINI, HASSAN, et al., "Protection against experimental autoimmune encephalomyelitis by a proteasome modulator", Journal of Neuroimmunology, 188, (2001),233-244	
		HSU, A., et al., "Ritonavir. Clinical pharmacokinetics and interactions with other anti-HIV agents", Clin Pharmacokinet, 35(6), (Abstract Only),(December 1998), 1 pg.	
		HUANG, L. , et al., "Efficient lipofection with cisplatin-resistant human tumor cells", Cancer Gene Therapy, 3(2), (1996),107-112	
		IQBAL, MOHAMED , et al., "Potent Inhibitors of Proteasome", Journal of Medicinal Chemistry, 38(13), (1995),2276-2277	
		ITANI, O. A., et al., "Cycloheximide Increases Glucocorticoid-Stimulated alpha-ENaC mRNA in Collecting Duct Cells by p38 MAPK-dependent Pathway", Am. J. Physiol. Renal Physiol., 284, (2002),F778-F787	
		JENSEN, T J., et al., "Multiple Proteolytic Systems, Including the Proteasome, Contribute to CFTR Processing", Cell, 83, (1995),pp. 129-135	
		JIANG, Q. , et al., "Cellular Heterogeneity of CFTR Expression and Function in the Lung: Implications for Gene Therapy of Cystic Fibrosis", European Journal of Human Genetics, 6, (January, 1998), 12-31	

EXAMINER **DATE CONSIDERED**

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional) 2 Applicant is to place a check mark here if English language Translation is attached

PTO/SB/08A(10-01)
Approved for use through 10/31/2002. OMB 651-0031
US Patent & Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known

Application Number	10/815,557
Filing Date	March 31, 2004
First Named Inventor	Engelhardt, John
Group Art Unit	1653
Examiner Name	Unknown

Sheet 9 of 16

Attorney Docket No: 875.085US1

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No [1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
		KAPLAN, JOHANNE M., et al., "Potentiation of gene transfer to the mouse lung by complexes of adenvirus vector and polycations improves therapeutic potential", Human Gene Therapy, 9(10), (July 1, 1998),1469-1479	
		KAZI, A. , et al., "Inhibition of the Proteasome Activity, a Novel Mechanism Associated with the Tumor Cell Apoptosis-Inducing Ability of Genistein", Biochemical Pharmacology, 66, (2003),965-976	
		KESSLER, P. , et al., "Sodium Butyrate Greatly Enhances the efficiency of Viral Transduction in Adult Ventricular Cardiomyocytes by Adeno-associated Viral Vectors", Circulation 92(8), (Abstract Only), (October 15, 1995),296	
		KIM, KYUNG BO, et al., "Proteasome Inhibition by the Natural Products Epoxomicin and Dihydroeponemycin: Insights into Specificity and Potency", Bioorganic & Medicinal Chemistry Letters, (1999),3335-3340	
		KIM, KOANHOI, "Proteasome Inhibitors Sensitize Human Vascular Smooth Muscle Cells to Fas (CD95) - Mediated Death", Biochemical and Biophysical Research Communications, 281(2), (2001),305-310	
		KIYOMIYA, KEN-ICHI, et al., "Mechanism of Specific Nuclear Transport of Adriamycin: The Mode of Nuclear Translocation of Adriamycin-Proteasome Complex", Cancer Research, (March 15, 2001),2467-2471	
		KIYOMIYA, K., et al., "The role of the proteasome in apoptosis induced by anthracycline anticancer agents", Int. J. Oncol., 20(6), (Abstract Only),(June 2002), 1 pg.	
		KIYOMIYA, KEN-ICHI , et al., "The Role of the Proteasome in apoptosis induced by anthracycline anticancer agents", International Journal of Oncology, 20 (6), ISSN: 1019-6439,(June 2002),1205-1209	
		KLOETZEL, P M., "The Proteasome system: a neglected tool for improvement of novel therapeutic strategies?", Gene Therapy, 5, (1998), 1297-1298	
		KUMAR, GITA , "Side-stepping the side effects", BioCentury, The Bernstein Report on BioBusiness, (December 17, 2001), 1 pg.	
		LEBKOWSKI, J., "Adeno-Associated Virus: a Vector System for Efficient Introduction and Integration of DNA into a Variety of Mammalian Cell Types", Molecular and Cellular Biology, 8(10), (October 1988),3988-3996	
		LEE, SANG GOO , et al., "Enhancement of adenoviral transduction with polycationic liposomes in vivo", Cancer Gene Therapy, 7(10), (2000),1329-1335	
		LEE, D. H., "Proteasome Inhibitors: Valuable New Tools For Cell Biologists", Trends in Cell Biology, 8, (October 1998), 397-403	
		LEE, DO HEE, et al., "Selective Inhibitors of the Proteasome-dependent and Vacuolar Pathways of Protein Degradation in *Saccharomyces cerevisiae*", Journal of Biological Chemistry, (November 1, 1996),27280-27284	
		LEE, DO HEE, et al., "Chapter 10 - The Proteasome Inhibitors and Their Uses", Proteasomes: The World of Regulatory Proteolysis, (2000),154-175	

EXAMINER **DATE CONSIDERED**

Substitute Disclosure Statement Form (PTO-1449)

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional) 2 Applicant is to place a check mark here if English language Translation is attached

PTO/SB/08A(10-01)
Approved for use through 10/31/2002. OMB 651-0031
US Patent & Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known	
Application Number	10/815,557
Filing Date	March 31, 2004
First Named Inventor	Engelhardt, John
Group Art Unit	1653
Examiner Name	Unknown

Sheet 10 of 16

Attorney Docket No: 875.085US1

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No [1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
		LIANG, E. , et al., "Oligonucleotide delivery: a cellular prospective", Pharmazie, 54(8), (Aug. 1999), 559-566	
		LU, WEI , et al., "HIV protease inhibitors restore impaired T-cell proliferative response in vivo and in vitro: a viral-suppression-independent mechanism", Blood, 96(1), (July 1, 2000), 250-258	
		LUO, HONGYU, et al., "A Proteasome Inhibitor Effectively Prevents Mouse Heart Allograft Rejection", Transplantation, 72(2), (July 27, 2001),196-202	
		MAH, C. et al., "Adeno-Associated Virus Type 2-Mediated Gene Transfer: Role of Epidermal Growth Factor Receptor Protein Tyrosine Kinase in Transgene Expression", Journal of Virology, 72(12), (1998),pp. 9835-9843	
		MAITRA, R. , et al., "Increased Functional Cell Surface Expression of CFTR and ΔF508-CFTR by the Anthracycline doxorubicin", Am. J. Physiol. Cell Physiol., 280, (May, 2001),C1031-C1037	
		MALIK, B. , et al., "ENaC Degradation in A6 Cells by the Ubiquitin-Proteosome Proteolytic Pathway", The Journal of Biological Chemistry, 276(16), (Apr. 20, 2001),12903-12910	
		MASTROIANNI, CLAUDIO M., et al., "Ex Vivo and In Vitro Effect of Human Immunodeficiency Virus Protease Inhibitors on Neutrophil Apoptosis", Journal of Infectious Diseases (182), (November 2000),1536-1539	
		MATTSSON, KARIN , et al., "Proteins associated with the promyelocytic leukemia gene product (PML)-containing nuclear body move to the nucleolus upon inhibition of proteaseome-dependent protein degradation", Proc. Natl. Acad. Sci., USA, 98(3), (January 30, 2001),1012-1017	
		MCAULIFFE, O. , et al., "Lantibiotics: Structure, Biosynthesis and Mode of Action", FEMS Microbiology Reviews, 25(3), (2001),285-308	
		MENG, LIHAO, et al., "Eponemycin Exerts Its Antitumor Effect through the Inhibition of Proteasome Function", Cancer Research, 59, (June 15, 1999), 2798-2801	
		MENG, L. , et al., "Epoxomicin, a potent and selective proteasome inhibitor, exhibits *in vivo* antiinflammatory activity", Proc. Natl. Acad. Sci. USA, 96(18), (August 31, 1999),10403-10408	
		MEYER, STEPHANIE, et al., "Cyclosporine A is an uncompetitive inhibitor of proteasome activity and prevents NF-κB activation", Federation of European Biochemical Societies, (1997),354-358	
		MOSNAIM, ARON , et al., "Degradation Kinetics of Leucine^5 -Enkephalin by Plasma Samples from Healthy Controls and Various Patient Populations: In Vitro Drug Effects", American Journal of Therapeutics, vol. 7, (2000),185-194	
		NAM, SANGKIL, et al., "Tannic Acid Potently Inhibits Tumor Cell Proteasome Activity, Increases p27 and Bax Expression, and Induces G_1 Arrest and Apoptosis", Cancer Epidemiology, Biomarkers & Prevention, 10, (October, 2001),1083-1088	

EXAMINER **DATE CONSIDERED**

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional) 2 Applicant is to place a check mark here if English language Translation is attached

PTO/SB/08A(10-01)
Approved for use through 10/31/2002. OMB 651-0031
US Patent & Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known	
Application Number	10/815,557
Filing Date	March 31, 2004
First Named Inventor	Engelhardt, John
Group Art Unit	1653
Examiner Name	Unknown

Sheet 11 of 16

Attorney Docket No: 875.085US1

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No [1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
		NEPKA, CHARITINI , et al., "Chemopreventive activity of very low dose dietary tannic acid administration in hepatoma bearing C3H male mice", Cancer Letters, vol. 141, (1999),57-62	
		NEPKA, CH. , et al., "Tannins, xenobiotic metabolism and cancer chemo-prevention in experimental animals", European Journal of Drug Metabolism and Pharmacokinetics, 24(2), (1999),183-189	
		NIELSEN, J. , et al., "Spironolactone-Mediated Downregulation of the Epithelial Sodium Channel (eNaC) in Rat Kidney", FASEB Journal, 15(1) (Abstracts Part I), Abstract No. 393.11,(2001), A432	
		OBIN, M., et al., "Neurite outgrowth in PC12 cells. Distinguishing the roles of ubiquitylation and ubiquitin-dependent proteolysis", Journal of Biological Chemistry, 274(17), (April 23, 1999),11789-11795	
		PALOMBELLA, VITO , et al., "Role of the proteasome and NF-κB in streptococcal cell wall-induced polyarthritis", Proc. Natl. Acad. Sci. USA, 95, (December 1998),15671-15676	
		PAOLINI, ROSSELLA , et al., "Ubiquitination and degradation of Syk and ZAP-70 protein tyrosine kinases in human NK cells upon CD16 engagement", Proc. Natl. Acad. USA, 98(17), (August 14, 2001),9611-9616	
		PARKER, J. S., et al., "Cellular Uptake and Infection by Canine Parvovirus Involves Rapid Dynamin-Regulated Clathrin-Mediated Endocytosis, Followed by Slower Intracellular Trafficking", Journal of Virology, 74(4), (2000),1919-1930	
		PETROV, VICTOR , et al., "Effect of Protease Inhibitors on Angiotensin-Converting Enzyme Activity in Human T-Lymphocytes", American Journal of Hypertension, 13(5), (May 2000),535-539	
		PICCININI, M. , et al., "The human 26S proteasome is a target of antiretroviral agents", AIDS, 16(5), (Abstract Only),(March 29, 2002), 1 pg.	
		PICKLES, R J., et al., "Limited Entry of Adenovirus Vectors into Well-Differentiated Airway Epithelium Is Responsible for Inefficient Gene Transfer", Journal of Virology, 72 (7), (1998),pp. 6014-6023	
		PRINCIOTTA, MICHAEL F., et al., "Cells adapted to the proteasome inhibitor 4-hydroxy-5-iodo-3-nitrophenylacetyl-Leu-Leu-leucinal-vinyl sulfone require enzymatically active proteasomes for continued survival", Proc. Acad. Sci. USA, 98(2), (January 16, 2001),513-518	
		PRYDZ, K , et al., "Effects of Brefeldin A on Endocytosis, and Transport to the Golgi Complex in Polarized MDCK Cells", The Journal of Cell Biology, 119 (2), (1992), 259-272	
		PUTTARAJU, M. , et al., "Spliceosome-mediated RNA *trans*-splicing as a tool for gene therapy", Nature Biotechnology, 17 (3), (March 1999), 246-252	

EXAMINER **DATE CONSIDERED**

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional) [2] Applicant is to place a check mark here if English language Translation is attached

PTO/SB/08A(10-01)
Approved for use through 10/31/2002. OMB 651-0031
US Patent & Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known

Application Number	10/815,557
Filing Date	March 31, 2004
First Named Inventor	Engelhardt, John
Group Art Unit	1653
Examiner Name	Unknown

Sheet 12 of 16

Attorney Docket No: 875.085US1

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No [1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
		QING, K. , et al., "Adeno-Associated Virus Type 2-Mediated Gene Transfer: Correlation of Tyrosine Phosphorylation of the Cellular Single-Stranded D Sequence-Binding Protein with Transgene Expression in Human Cells In Vitro and Murine Tissues In Vivo", Journal of Virology, 72 (2), (Feb. 1998),pp. 1593-1599	
		QING, K. , et al., "Human fibroblast growth factor receptor 1 is a co-receptor for infection by adeno-associated virus 2", Nature Medicine, 5 (1), (Jan. 1999),pp. 71-77	
		QING, K. , "Role of tyrosine phosphorylation of a cellular protein in adeno-associated virus 2-mediated transgene expression", Proc. Natl. Acad. Sci. USA, 94, (September, 1997), 10879-10884	
		RAO, SHARMILA, et al., "Lovastatin-mediated G_1 arrest is through inhibition of the proteasome, independent of hydroxymethyl glutaryl-CoA reductase", Proc. Natl. Acad. Sci. USA, 96, (July 1999),7797-7802	
		RENDAHL, K. G., et al., "Regulation of Gene Expression in vivo Following Transduction by Two Separate rAAv Vectors", Nature Biotechnology, 16, (1998),757-761	
		RICHARDS, R. G., et al., "E2-Induced Degradation of Uterine Insulin Receptor Substrate-2: Requirement for an IGF-I-Stimulated, Proteasome-Dependent Pathway", Endocrinology, 142(9), (September 2001), 3842-3849	
		ROCK, K L., et al., "Inhibitors of the Proteasome Block the Degradation of Most Cell Proteins and the Generation of Peptides Presented on MHC Class I Molecules", Cell, 78, (1994), 761-771	
		RUSSELL, D W., et al., "DNA synthesis and topoisomerase inhibitors increase transduction by adeno-associated virus vectors", Proc. Natl. Acad. Sci., 92, (1995), 5719-5723	
		SANLIOGLU, S , et al., "Cellular redox state alters recombinant adeno-associated virus transduction through tyrosine phosphatase pathways", Gene Therapy, 6, (1999),pp. 1427-1437	
		SANLIOGLU, S. , et al., "Endocytosis and Nuclear Traffickling of Adeno-Associated Virus Type 2 Are Controlled by Rac1 and Phosphatidylinositol-3 Kinase Activation", Journal of Virology, 74(19), (2000),9184-9196	
		SANLIOGLU, S., et al., "Lipopoolysaccharide Induces Rac1-Dependent Reactive Oxygen Species Formation and Coordinates Tumor Necrosis Factor-alpha Secretion Through IKK Regulation of NF-κB", The Journal of Biological Chemistry, 276(32), (2001),30188-30198	
		SANLIOGLU, S., et al., "Loss of ATM Function Enhances Recombinant Adeno-Associated Virus Transduction and Integration Through Pathways Similar to UV Irradiation", Virology, 268, (2000),68-78	

EXAMINER **DATE CONSIDERED**

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional) 2 Applicant is to place a check mark here if English language Translation is attached

PTO/SB/08A(10-01)
Approved for use through 10/31/2002. OMB 651-0031
US Patent & Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known	
Application Number	10/815,557
Filing Date	March 31, 2004
First Named Inventor	Engelhardt, John
Group Art Unit	1653
Examiner Name	Unknown

Sheet 13 of 16

Attorney Docket No: 875.085US1

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No [1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T [2]
		SANLIOGLU, S. , et al., "Rate Limiting Steps of AAV Transduction and Implications for Human Gene Therapy", Current Gene Therapy, 1, (2001),137-147	
		SANLIOGLU, S. , et al., "Two Independent Molecular Pathways for Recombinant Adeno-Associated Virus Genome Conversion Occur After UV-C and E4orf6 Augmentation of Transduction", Human Gene Therapy, 10(4), (1999),591-602	
		SASAKI, T. , et al., "Inhibitory Effect of di- and Tripeptidyl Aldehydes on Calpains and Cathepsins", Journal of Enzyme Inhibition, 3(3), (1990),195-201	
		SCHWARTZ, O , et al., "Antiviral Activity of the Proteasome on Incoming Human Immunodeficiency Virus Type 1", Journal of Virology, 72 (5), (1998), 3845-3850	
		SCHWARTZ, DONALD , et al., "The neutral cysteine protease bleomycin hydrolase is essential for epidermal integrity and bleomycin resistance", Proc. National Academy of Science USA, vol. 96, (April 1999),4680-4685	
		SCHWARZ, KATRIN , et al., "The Selective Proteasome Inhibitors Lactacystin and Epoxomicin can be used to either Up- or Down-Regulate Antigen Presentation at Nontoxic Doses", Journal of Immunology, (2000),6147-6157	
		SHAH, SHIMUL , et al., "26S Proteasome Inhibition Induces Apoptosis and Limits Growth of Human Pancreatic Cancer", Journal of Cellular Biochemistry, vol. 82, (2001),110-122	
		SMITH, H. , et al., "Effect of a cancer cachectic factor on protein synthesis/degradation in murine C2C12 myoblasts: modulation by eicosapentaenoic acid", Cancer Res., 59(21), (Abstract Only),(November 1999), 1 pg.	
		SMITH, ANDREW, et al., "The Role of the Epidermal Growth Factor Receptor in Recombinant Adeno-Associated Virus Type-2 Mediated Transgene Expression in Lung Epithelial Cells", Molecular Therapy, 5(5), (Abstract No. 568),(May 2002), pg. S186	
		SON, KYONGHEE , et al., "Exposure of human ovarian carcinoma to cisplatin transiently sensitizes the tumor cells for liposome-mediated gene transfer", Proc. Natl. Acad. Sci. USA, 91, (December 1994), 12669-12672	
		SON, K., et al., "Factors influencing the drug sensitization of human tumor cells for in situ lipofection", Gene Therapy(3), (1996), 630-634	
		SON, KYONGHEE, et al., "Nitric oxide-mediated tumor cell killing of cisplatin-based interferon-γ gene therapy in murine ovarian carcinoma", Cancer Gene Therapy, 7(10), (2000),1324-1328	
		SPINDLER, B. , et al., "Characterization of Early Aldosterone-induced RNAs identified in A6 Kidney Epithelia", Pfluegers Archiv, Vol. 434, Springer Verlag, Berlin, DE (1997),323-331	

EXAMINER **DATE CONSIDERED**

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known	
Application Number	10/815,557
Filing Date	March 31, 2004
First Named Inventor	Engelhardt, John
Group Art Unit	1653
Examiner Name	Unknown

Sheet 14 of 16

Attorney Docket No: 875.085US1

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	**Cite No [1]**	**Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.**	**T[2]**
		STAUB, O., "Chapter 5 Regulation of ENaC by Interacting Proteins and by Ubiquitination", Current Topics in Membranes, 47 - Amiloride-Sensitive Sodium Channels - Physiology and Functional Diversity, Edited by Dale J. Benos, Academic Press, Publisher,(1999),65-87	
		STAUB, O., "Regulation of Stability and Functional of the Epithelial Na^+ Channel (ENaC) by Ubiquitination", The EMBO Journal, 16(21), (1997),6325-6336	
		STOCKAND, J. D., et al., "Targeted Degradation of the Epithelial Na Channel (ENaC) in Response to PKC Activation of the MAPK 1/2 Cascade", The FASEB Journal, 17(5), Abstracts (Part II), (Abstract No. 585.7),(2003), pg. A913	
		STOKES, J. B., "Regulation of rENac mRNA by Dietary NaCl and Steroids: Organ, Tissue, and Steroid Heterogeneity", American Journal of Physiology, Cell Physiology, 274, (1998),C1699-C1707	
		SWINNEY, DAVID C., et al., "Targeting protein ubiquitination for drug discovery. What is in the drug discovery toolbox?", DDT, 6(5), (March, 2001), 244-250	
		TAJIMA, KIMIHISA, et al., "The proteasome inhibitor MG132 promotes accumulation of the steroidogenic acute regulatory protein (StAR) and steriodogenesis", Federation of European Biochemical Societies, 490, (January 24, 2001), 59-64	
		TEODORI, L. , et al., "Reduction of 1-beta-D-arabinofuranosylcytosine and adriamycin cytotoxicity following cell cycle arrest by anguidine", Cancer Res., 41(4), (Abstract Only),(April 1981),1 pg.	
		TERAMOTO, S., et al., "Factors influencing adeno-associated virus-mediated gene transfer to human cystic fibrosis airway epithelial cells: comparison with adenovirus vectors", Journal of Virology, 72(11), (Nov., 1998), 8904-8912	
		TWEEDALE, TONY , "[Dioxin-l] Inhibits Estrogen-Induced Breast Cancer Cell Proliferation", Reuters Health, http//lists.essential.org/pipermail/dioxin-l/Week-of-Mon-2000103/000096.html,(December 1999), 1 pg.	
		VAN KERKHOF, PETER, et al., "Proteasome Inhibitors Block a Late Step in Lysosomal Transport of Selected Membrane but not Soluble Proteins", Molecular Biology of the Cell, vol. 12, (August 2001),2556-2566	
		VIHINEN-RANTA, M , et al., "Intracellular Route of Canine Parvovirus Entry", Journal of Virology, 72(1), (1998), 802-806	
		VILLANI, P., et al., "Antiretrovirals: Simultaneous determination of five protease inhibitors and three nonnucleoside transcriptase inhibitors in human plasma by a rapid high-performance liquid chromatography-mass spectrometry assay", The Drug Monit., 23(4), (Abstract Only),(August 2001),1 pg.	
		WALTERS, R W., et al., "Basolateral localization of fiber receptors limits adenovirus infection from the apical surface of airway epithelia", The Journal of Biological Chemistry, 274(15), (April 9, 1999),10219-10226	

EXAMINER **DATE CONSIDERED**

PTO/SB/08A(10-01)
Approved for use through 10/31/2002. OMB 651-0031
US Patent & Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known	
Application Number	10/815,557
Filing Date	March 31, 2004
First Named Inventor	Engelhardt, John
Group Art Unit	1653
Examiner Name	Unknown

Sheet 15 of 16

Attorney Docket No: 875.085US1

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	**Cite No [1]**	**Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.**	**T[2]**
		WALTERS, R W., et al., "Incorporation of Adeno-Associated Virus in a Calcium Phosphate Coprecipitate Improves Gene Transfer to Airway Epithelia In Vitro and In Vivo", Journal of Virology, 74 (1), (2000),535-540	
		WESTFALL, T. D., et al., "The Ecto-ATPase Inhibitor ARL 67156 Enhances Parasympathetic Neurotransmission in the Guinea-Pig Urinary Bladder", European Journal of Pharmacology, 329, (1997),169-173	
		WHITEHOUSE, ALISON , et al., "Downregulation of Ubiquitin-Dependent Proteolysis by Eicosapentaenoic Acid in Acute Starvation", Biochemical and Biophysical Research Communications, 285(3), (2001),598-602	
		WICKHAM, T J., et al., "Adenovirus targeted to heparan-containing receptors increases its gene delivery efficiency to multiple cell types", Nature Biotechnology, 14, (1996),1570-1573	
		WICKHAM, T J., et al., "Targeted Adenovirus Gene Transfer to Endothelial and Smooth Muscle Cells by Using Bispecific Antibodies", Journal of Virology, 70 (10), (1996), 6831-6838	
		WOESSNER, RICHARD , et al., "Comparison of Three Approaches to Doxorubicin Therapy: Free Doxorubicin, Liposomal Doxorubicin, and β-Glucuronidase-Activated Prodrug (HMR 1826)", Anticancer Research, (2000),2289-2296	
		WOJCIK, "Inhibition of the proteasome as a therapeutic approach", Drug Discovery Today, 4 (4), (April 1999), 188-189	
		WOJCIK, CEZARY , et al., "Lovastatin and simvastatin are modulators of the proteasome", International Journal of Biochemistry & Cell Biology, (32), (2000),957-965	
		WORKING, PETER, et al., "Pharmacological-Toxicological Expert Report CAELYX™ (Stealth Liposomal Doxorubicin HCl)", Human & Experimental Toxicology, (1996),752-785	
		XIAO, W., et al., "Adeno-Associated Virus as a Vector for Liver-Directed Gene Threapy", Journal of Virology, 72 (12), (1998),pp. 10222-10226	
		YAN, Z. , et al., "[20] Recombinant AAV-Mediated Gene Delivery Using Dual Vector Heterodimerizatiion", In: Methods in Enzmology, Vol. 346: Gene Therapy Methods, Phillips, M. I., Editor, Academic Press, San Diego, CA,(2002),334-357	
		YAN, ZIYING, et al., "A Common Theme for Ubiquitination-Dependent Transduction of rAAV Type 2 and 5", American Society of Gene Therapy, Abstracts of Scientific Presentations, (Abstract No. 569),(June 5, 2002), 1 pg.	
		YAN, Z. , et al., "Distinct Classes of Proteasome-Modulating Agents Cooperatively Augment Recombinant Adeno-Associated Virus Type 2 and Type 5-Mediated Transduction From the Apical Surfaces of Human Airway Epithelia", Journal of Virology, 78(6), (March, 2004),2863-2874	

EXAMINER **DATE CONSIDERED**

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional) [2] Applicant is to place a check mark here if English language Translation is attached

PTO/SB/08A(10-01)
Approved for use through 10/31/2002. OMB 651-0031
US Patent & Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known	
Application Number	10/815,557
Filing Date	March 31, 2004
First Named Inventor	Engelhardt, John
Group Art Unit	1653
Examiner Name	Unknown

Sheet 16 of 16

Attorney Docket No: 875.085US1

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	**Cite No [1]**	**Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.**	**T[2]**
		YAN, Z , et al., "Trans-splicing vectors expand the utility of adeno-associated virus for gene therapy", Proc. Natl. Acad. Sci. USA, 97, (June 6, 2000),6716-6721	
		YANG, J. , et al., "Concatamerization of Adeno-Associated Virus Circular Genomes Cccurs Through Intermolecular Recombination", Journal of Virology, 73 (11), (Nov. 1999),9468-9477	
		ZABNER, J , et al., "Adenovirus-mediated gene transfer to ciliated airway epithelia requires prolonged incubation time", Journal of Virology, 70(10), (October, 1996),6994-7003	
		ZABNER, J , et al., "Adenovirus-mediated generation of cAMP-stimulated Cl- transport in cystic fibrosis airway epithelia in vitro: effect of promoter and administration method", Gene Therapy, 3, (1996),pp. 458-465	
		ZENTNER, M. D., "The Amiloride-Sensitive Epithelial Sodium Channel a-Subunit is Transcriptionally Down-Regulated in Rat Parotid Cells by the Extracellular Signal-Regulated Protein Kinase Pathway", The Journal of Biological Chemistry, 273(46), (1998),30770-30776	
		ZHOU, LIQIAO , et al., "Improvement of Transduction Efficiency from Split AAV Vectors", American Society of Gene Therapy, (Abstract Only), Abstracts of Scientific Presentations, (June 5, 2002), 1 pg.	

EXAMINER **DATE CONSIDERED**

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional) [2] Applicant is to place a check mark here if English language Translation is attached